SEP - 6 2001

K012360

parkell

510(k) SUMMARY

Submitter:

Parkell, Inc.
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735
TEL: 631-249-1134
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Contact:

Nelson J. Gendusa, DDS
Director of Research
Parkell
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735

Submission Date: 18 July 2001

Trade Name: LC Temporary Material

Common Name: Light Cured Temporary Filling Material

Classification Name: Temporary Crown & Bridge Resin

Equivalence: Fermit N, Tempfil F, Tempfil C&B, Tempfil F-2, LC Provifill.

Description/Intended Use: A light-cured resin intended for use as a temporary restorative material in a tooth prepared to receive an inlay or onlay until such time as the laboratory fabricated final restoration can be inserted into that tooth.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Nelson J. Gendusa, DDS
Director of Research
Parkell, Incorporated
155 Schmitt Boulevard
P.O. Box 376
Farmingdale, New York 11735

Re: K012360
Trade/Device Name: LC Temporary Filling
Regulation Number: 21 CFR 872.3770
Regulation Name: Light-Cured Temporary Filling Materials
Regulatory Class: Class II
Product Code: EBG
Dated: July 18, 2001
Received: July 25, 2001

Dear Dr. Gendusa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

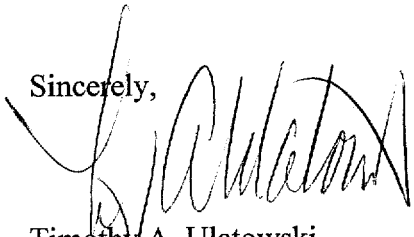
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k Number (if known): K012360

Device Name: LC Temporary Filling

Indications for Use: A light-cured resin intended for use as a temporary restorative material in a tooth prepared to receive an inlay or onlay until such time as the laboratory fabricated final restoration can be inserted into that tooth.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012360